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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,247	01/14/2002	Adolfo Goren	P 0280702	1041

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,247	GOREN ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *1-7,11,14-38,41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,12,13,39,40 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed August 28, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 1-43 are pending.

3. In the reply filed on May 18, 2005, applicant elected of Group II, claims 8-13 and 29-42 (now including claim 43), *Allium cepa* for species A and rhinovirus for species B **without** traverse.

4. Claims 1-7, 11, 14-38, 41, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 18, 2005.

5. Claims 8-10, 12, 13, 39-40 and 43 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8-10, 12, 13, 39-40 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 8 to state that the viral infection is treated with

a composition comprising greater than 95% of the particulate material from *Allium cepa*. However, applicant's specification does not support the use of a composition comprising the specific percentage of *Allium cepa*. The specification discusses a percentage of greater than 95% in regards to the particle sizes being between 1 to 1,4000 microns. Specifically, the specification states "Preferably, the utilize procedure for particulating the processed dehydrated *Allium*, preferably *Allium cepa*, material will result in most (greater than 95%) of the particles or granules in the resultant composition having an average size ranging from 1 to 1,400 microns...(see page 11, lines 5-8)." The specification does not support including the *A. cepa* in the pharmaceutical composition at amounts greater than 95% only that the particle distribution is at least 95% between 1 to 1,400 microns. Thus, the addition of the limitation requiring 95% of *A. cepa* in the pharmaceutical composition does not have support in the specification as originally filed. The specification does discuss specific dosage of *A. cepa* to administer, but does not state the percentage of *A. cepa* in these dosages.

Claim Rejections - 35 USC § 103

7. Claims 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach using onion in the amounts claimed by applicant. However, the reference teaches only specifically mentions onion as one active ingredient in the method to treat the common cold. The reference does not

specifically teach the percentage of onion included in the compositions. However, the dosage of a specific ingredient is well known in the art to be a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount dosage of onion to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

8. Claims 8-10, 12, 13, 39-40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that CN '152 teaches away from using a high dosage of onion in the composition based on the "significant amount" of other material included in the composition of CN '152. However, CN '152 is not considered by the examiner to require a "significant amount" of material other than the onion. The reference teaches only one active ingredient, onion, and states that this can be administered in various pharmaceutical forms. No other ingredients are specifically required. Thus, CN '152 is not considered to teach

away from using a high dosage of onion. Therefore, the claims are considered properly rejected for the reasons of record.

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHoffman
11-8-06

Susan Coe Hoffman
Primary Examiner
Art Unit 1655